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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,925	04/20/2004	Enrico Cappelleti	57637/1380	5906

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EXAMINER	
JONES, DAMERON LEVEST	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
07/31/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

klpatent@kramerlevin.com

Office Action Summary	Application No.	Applicant(s)	
	10/828,925	CAPPELLETI ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-107* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESTRICTION INTO GROUPS

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 15, 46, 48, 50, 72, 76, 78, 79, 82, 83, 87, and 100, drawn to compounds (and methods of making the compounds thereof) of general formula MNOPG wherein an alpha or non-alpha amino acid (without a cyclic group) is present, classified in class 424, subclass 1.69.

II. Claims 1, 8, 11-14, and 47, drawn to a method of imaging using the compounds of formula MNOPG wherein an alpha or non-alpha amino acid is present, classified in class 424, subclass 9.1.

III. Claims 4, 7-9, 16, 17, 46, 49, 51, 86, and 100, drawn to a method of treating a subject using a radiotherapeutic agent of formula MNOPG wherein an alpha or non-alpha amino acid (with a cyclic group) is present, classified in class 514, subclass 14.

IV. Claims 4, 7-9, 18-33, 38, 40, 41, 71, 73-75, 77, 80, 81, 87, and 100, drawn to compounds (and methods of making the compounds) having the general formula MNOPG wherein a substituted bile acid is present, classified in class 424, subclass 1.45.

V. Claims 20, 32-37, and 42, drawn to a method of imaging the compounds encompassed by the formula MNOPG wherein a substituted bile acid is present, classified in class 424, subclass 1.45.

VI. Claims 20, 39, 41, 44, and 86, drawn to a method of treating a patient with a radiotherapeutic agent encompassed within claim 17

wherein a substituted bile acid is present, classified in class 514, subclass 2.

VII. Claims 51-64 and 68, drawn to compounds (and methods of making the compounds) having the formula MNOPG wherein an alpha amino acid or non-alpha amino acid with a cyclic group, classified in class 424, subclass 1.69.

VIII. Claims 51, 63, and 65-67, drawn to a method of imaging using compounds encompassed by MNOPG wherein an alpha amino acid or non-alpha amino acid with a cyclic group is present, classified in class 424, subclass 9.1.

IX. Claims 51, 69, 70, and 86, drawn to a method of treating a subject by administering a radiotherapeutic agent encompassed by MNOPG wherein an alpha amino acid or non-alpha amino acid with a cyclic group is present, classified in class 514, subclass 2.

X. Claims 1, 84, and 85, drawn to a method of phototherapy comprising a compound of formula MNOPG wherein an alpha amino or non-alpha amino acid without a cyclic group is present, classified in class 514, subclass 2.

XI. Claims 20 and 84, drawn to a method of phototherapy comprising a compound of formula MNOPG wherein an alpha amino or non-alpha amino acid with a bile acid is present, classified in class 514, subclass 2.

XII. Claims 51and 84, drawn to a method of phototherapy comprising a compound of formula MNOPG wherein an alpha amino or non-alpha amino acid with a cyclic group, classified in class 514, subclass 2.

XIII. Claims 88, 90, and 93, drawn to a method of targeting the gastrin releasing peptide receptor and neuromedin-B receptor using compounds of formula MNOPG wherein an alpha amino or non-alpha amino acid without a cyclic group is present, classified in class 424, subclass 1.11.

XIV. Claims 88, 89, and 93, drawn to a method of targeting the gastrin releasing peptide receptor and neuromedin-B receptor using compounds of formula MNOPG wherein an alpha amino or non-alpha amino acid with a cyclic group is present, classified in class 424, subclass 1.11.

XV. Claims 91-93, drawn to a method of targeting gastrin releasing peptide receptor and neuromedin-B receptor using compounds of formula MNOPG wherein a non-alpha amino acid without a cyclic group, classified in class 424, subclass 1.11.

XVI. Claims 1, 78, 82, 94, 95, 99, and 106, drawn to a method of improving in vivo activity of a compound of formula MNOPG wherein an alpha or non-alpha amino acid without a cyclic group is present, classified in class 424, subclass 1.11

XVII. Claims 51, 94, 95, and 99, drawn to a method of improving in vivo activity of a compound of formula MNOPG wherein an alpha or non-alpha

amino acid with a cyclic group is present, classified in class 424, subclass 1.11.

XVIII. Claims 20, 80, 94, 95, 99, a, drawn to a method of improving in vivo activity of a compound of formula MNOPG wherein a bile acid is present, classified in class 424, subclass 1.11.

XIX. Claims 1, 78, 82, and 96-99, drawn to a method of reducing proteolytic cleavage of a gastrin releasing peptide wherein an alpha or non-alpha amino acid without a cyclic group is present, classified in class 424, subclass 1.11.

XX. Claims 20 and 96-99, drawn to a method of reducing proteolytic cleavage of a gastrin releasing peptide wherein an alpha or non-alpha amino acid with a cyclic group is present, classified in class 424, subclass 1.11.

XXI. Claims 51, 80, and 96-99, drawn to a method of reducing proteolytic cleavage of gastrin releasing peptide wherein a bile acid is present, classified in class 424, subclass 1.11.

XXII. Claim 101, drawn to a method of conferring specificity wherein a non-alpha amino acid without a cyclic group is present, classified in class 424, subclass 1.11.

XXXIII. Claim 103, drawn to a method of conferring specificity wherein a non-alpha amino acid with a cyclic group is present, classified in class 424, subclass 1.11.

XXXIV. Claim 102, drawn to a method of conferring specificity wherein a bile acid is present, classified in class 424, subclass 1.11.

XXXV. Claim 104, drawn to a method of improving stability of a compound wherein a non-alpha amino acid without a cyclic group is present, classified in class 424, subclass 1.11.

XXXVI. Claim 107, drawn to a compound as set forth in independent claim 107, classified in class 424, subclass 1.11.

Note: Claims appearing in more than one Group will only be examined to the extent that they read on the elected invention.

2. Inventions (I and II), (I and III), (IV & V), (IV & VI), (VII & VIII), (VII & IX), (I & X), (IV & XI), (IV & XI), (VII & XIII), (VII & XIV), (I & XV) (I & XVII), (IV & XX), (I & XXI), (I & XXII), (VIII & XXIII), (IV & XXIV), (I & XXXV), and (XXXVI & I) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the compounds may be used for imaging purposes, treating a subject, phototherapy, targeting the gastrin releasing peptide receptor and neuromedin-B receptor, improving in vivo activity of a compound, improving in vivo stability, and reducing proteolytic cleavage, as well as other methods.

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

ELECTION OF SPECIES

4. Claims 1-107 are generic to the following disclosed patentably distinct species comprising bile acid and non-alpha amino acid with and without a cyclic group. The compounds comprise various components such as an optical label, a metal chelator, a radionuclide, linking groups, peptides, non-alpha amino acids with and without cyclic groups, bile acids, etc.. The species are independent or distinct because one group of species would neither anticipate nor render obvious another group of species.

5. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

***Note**: The Examiner respectfully requests that the Applicant elect a single disclosed species from within the elected Group above. In particular, Applicant is*

respectfully requested to elect a specific sequence identification number, a chelator, optical label, radionuclide, linking group, etc. and state which claims are drawn to the elected species.

6. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. Due to the complexity of the restriction requirement, a telephone call was not made to request an oral election to the above restriction requirement.

8. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

9. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

10. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

REJOINDER PARAGRAPH

12. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D. L. Jones
Primary Examiner
Art Unit 1618

July 22, 2007